UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

## MEMORANDUM

**SUBJECT:** Science Review in Support of the Registration of B2E-02, Containing 39.2% (S)-Methoprene [Isopropyl (2E,4E,7S)-methoxy-3,7,11-trimethyl-2,4-dodecadienoate] As Its Active Ingredient. Review of Estimated Environmental Concentration (EEC) Data.

End-Use Product (EP) Registration No.: 75318-1
Active Ingredient (AI) PC Code: 105402, Registration No. 70432-1
DP Barcode: 328194
Decision No.: 364346
MRID No.: 46750301

**FROM:** Angela L. Gonzales, Biologist Angela L. Gonzales
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

**TO:** Mari Duggard, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

## ACTION REQUESTED

B2E Biotech LLC requests an amendment to include aquatic-use sites on the label of B2E-02 (EPA Reg. No. 75318-1), an end-use product (EP) containing 39.2% (S)-Methoprene [Isopropyl (2E,4E,7S)-methoxy-3,7,11-trimethyl-2,4-dodecadienoate], an insect growth regulator (IGR), as its active ingredient. Estimated environmental concentration (EEC) data regarding the AI were submitted in MRID 46750301 and are discussed in this memorandum.

## RECOMMENDATIONS AND CONCLUSIONS

MRID 46750301- EEC Determination for (S)-Methoprene in B2E-02- **ACCEPTABLE**, pending resolution of issues listed below.

1. The registrant must clarify if there is a difference between the "wettable powder" termed on the label as the EP and in MRID 46750301 as the test substance, and the "water soluble pouch", which is also used on the label and in the EEC data.

2. The submitted data establish (S)-methoprene concentrations at lesser levels after 24 hours post-application than the lowest observed effect concentration (LOEC) of 2.0 ppb on Mysid shrimp (*Mysidopsis bahia*), determined by BPPD and discussed in a memorandum from A. L. Gonzales to M. Duggard dated February 17, 2005.

   a. It is noted that the mean concentration of the TGAI was reported to be 3.43 ppb at one hour post-application, which is higher than the LOEC of 2.0 ppb. However, at 24 hours the mean concentration was reported at 0.53 ppb; therefore, due to the minimal length of exposure at the higher concentration, adverse reproductive effects to aquatic invertebrates are not likely to occur if the product is used according to label instructions.

3. The label instructions provide information and guidance for the EP to be formulated into granules. EEC data were only provided and discussed for the water soluble pouch formulation. The registrant must address the granular formulation with respect to EEC determination because the granular product may have a different release rate than the water soluble pouch product.

## STUDY SUMMARIES

Ecotoxicology (MRID 46750301)

Estimated Environmental Concentration (EEC) of (S)-Methoprene Determination

(S)-Methoprene concentrations were ascertained from B2E-02 applications to three test sites: 1) coastal salt marsh 2) permanent fresh water and 3) intermittent flood water. Initial location sizes ranged from 972ft$^2$ to 23,220ft$^2$ with water depths averaging from 1.0ft to 3.0ft. The EP was applied once at each site at the maximum application rate (4 pouches/5 acres or 0.10lbs/acre) according to label instructions. Two water samples were collected from each of two locations from each site at one hour before application, one hour after application and 24, 48, 72, 96, 120, 144 and 168 hours after application. Samples were extracted within two hours of collection using dichloromethane. Analysis of (S)-Methoprene concentrations was performed by capillary gas chromatography with flame ionization detection. Methods were validated with a 96.0% w/w (S)-Methoprene reference standard. Water quality samples (pre-treatment) were analyzed within two hours of collection for pH, hardness, alkalinity and total dissolved solids. Mean levels of the TGAI concentrations in each test site are presented in Table 1:

Table 1. Mean Concentrations of (S)-Methoprene in Test Sites*

| Hours after application | Salt (μg/L) | Fresh (μg/L) | Flood (μg/L) | Mean[a] (μg/L) | Upper Limit[b](μg/L) |
|---|---|---|---|---|---|
| -1 | --** | -- | 0.42 | 0.31 | 0.40 |
| 1 | 5.78 | 1.83 | 2.69 | 3.43 | 5.87 |
| 24 | 0.40 | 0.80 | 0.39 | 0.53 | 0.83 |
| 48 | -- | 0.29 | 0.37 | 0.31 | 0.43 |
| 72 | 0.31 | 0.33 | -- | 0.30 | 0.37 |
| 96 | 0.60 | 0.32 | -- | 0.39 | 0.57 |
| 120 | 0.38 | 0.42 | 0.27 | 0.34 | 0.46 |
| 144 | 0.27 | -- | -- | 0.26 | 0.27 |
| 168 | -- | -- | -- | 0.26 | 0.26 |

*Data reproduced from MRID 46750301

** -- = < 0.257μg/L, which is the minimum quantifiable level (used for mean calculations)

[a] Overall average of results from all sites

[b] Based on 95% Confidence Interval (P = 0.05) (using entire data set)

The overall average concentration of (S)-Methoprene was determined to be 3.43μg/L at the initiation of the study (one hour after application) and 0.26μg/L at the conclusion (168 hour post-treatment) of the study. Based on the data submitted, calculated concentrations of the TGAI after 24 hours are lower than the LOEC of 2.0 ppb (μg/L) for Mysid shrimp (*Mysidopsis bahia*), determined by BPPD and discussed in a memorandum from A. L. Gonzales to M. Duggard dated February 17, 2005. It is noted that the concentration of the TGAI is higher than the LOEC of 2.0 ppb at one hour post-application. However, at 24 hours the mean concentration was reported at 0.53 ppb; therefore, due to the minimal length of exposure at the higher concentration, adverse reproductive effects to aquatic invertebrates are not likely to occur if the product is used according to label instructions.

cc: A. Gonzales, M. Duggard, BPPD Subject File, IHAD/ARS
A. Gonzales, FT, CM2, 04/13/2006

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# R153103

**Chemical:** S-Methoprene

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**HED File Code:** 41500 BPPD Tox/Chem
**Memo Date:** 4/13/2006
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**Accession #:** 000-00-9003

**HED Records Reference Center**
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